

Applicants: Elena Feinstein and Orna Mor  
Serial No.: 09/825,682  
Filed: April 4, 2001  
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REMARKS

Claims 1, 2, 4-6, 24, 26, and 27 were pending in the subject application. Applicants hereinabove have amended claims 1 and 6 and added claims 30-31. Accordingly, claims 1, 2, 4-6, 24, 26-27, and 30-31 are now pending and presented for the Examiner's consideration.

Support for amended claim 1 can be found *inter alia* on page 37, line 15; page 51, line 2; and page 67, line 40 of the specification.

Support for newly added claims 30 and 31 can be found *inter alia* in Table 5, page 95 of the specification.

Information Disclosure Statement

On page 3 of the May 10, 2004 Office Action, the Examiner stated that the IDS filed on September 12, 2003 contained no copy of the reference entitled: American Cancer Society, "Estimating New Cancer Cases and Deaths By Sex For All Sites," *Cancer Facts and Figures*, pg 4 (1998.)

Applicants respectfully submit that the above-identified reference was filed with the U.S. Patent and Trademark Office on March 7, 2001 as part of the Information Disclosure Statement in corresponding U.S. Application Serial No. 09/670,672. As evidence of such deposit, applicant annexes hereto as **Exhibit A** a copy of the return postcard originally submitted with the subject Information Disclosure Statement and marked by the U.S. Patent and Trademark Office. By marking the return postcard, without further annotation, the U.S. Patent and Trademark Office has provided *prima facie* evidence of receipt of all papers set forth on the postcard (M.P.E.P. §503) including, in relevant part, the References which includes the above-identified reference. Hence,

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the return postcard is *prima facie* evidence that the above-identified reference was in fact deposited on March 7, 2001 with the U.S. Patent and Trademark Office.

Nevertheless, applicants, without conceding the omission of the above-identified reference from the Information Disclosure Statement in corresponding U.S. Application Serial No. 09/670,672, but in order to expedite prosecution of the subject application and insure compliance with their duty of disclosure under 37 C.F.R. §1.56, attach a new PTO Form 1449 as **Exhibit B** listing the purportedly missing reference, and a copy of the reference as **Exhibit 1** thereto.

Applicants request that the Examiner consider this reference and make it of record by initialing the enclosed PTO Form 1449.

**Claim Rejections: 35 U.S.C. 112**

In the May 10, 2004 Office Action, the Examiner rejected claims 1-2, 4-6, 24 and 26-27 under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement.

The Examiner noted that applicants' amendments have overcome the instant rejection in part. Particularly, the pending claims no longer encompass detection of the sequences of the claims as indicators of stage Ta and/or stage T1 bladder cancer/TCC. However, the Examiner alleged that the claims as written encompass detection of increased expression of molecules other than SEQ ID NOs. 56, 57, and 41, and continue to encompass diagnosis of bladder cancer in non-human patients.

In response, applicants have amended claim 1 to specifically recite SEQ ID NOs 56, 57, and 41 and diagnosis of bladder cancer in human patients. Claims 2, 4-6, 24, and 26-27 depend on claim 1. Applicants therefore believe that the pending claims as amended comply under 35 U.S.C. 112, first paragraph, and

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respectfully request reconsideration and withdrawal of the Examiner's ground of rejection, and allowance of the claims.

The Examiner also stated that claim 6 is rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner noted that the claim has been amended to recite "the determining step" in lieu of "the analyzing step," thereby overcoming a rejection made in the prior Office Action. However, the Examiner alleged that the "determining" step of claim 1 does not refer to a single "polynucleotide," but only multiple "polynucleotides." Accordingly, the Examiner alleged that the recitation of "said polynucleotide" in claim 6 lacks antecedent basis.

In response, claim 6 has been amended to recite one of said polynucleotides.

Applicants maintain that the amendment to claim 6 does not raise any issue of new matter and renders claim 6 no longer subject to rejection under 35 U.S.C. 112, second paragraph.

Finally, applicants note that new claims 30 and 31 merely add specific reference to specific genes associated with SEQ ID NOS 57 and 56.

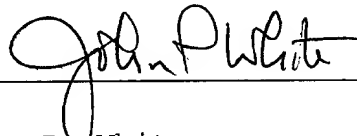
In conclusion, based on amendments to the claims and the remarks presented above, applicants respectfully request reconsideration of the rejections set forth in the May 10, 2004 Office Action and earnestly solicit allowance of the now pending claims, i.e. claims 1, 2, 4-6, 9, 24, 26, 27, and 30-31.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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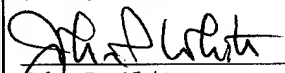
No fee, other than the enclosed \$55.00 fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

 8/19/04  
John P. White Date  
Reg. No. 28,678